Amendments to the Specification

Please replace the title of the application at page 1, line 1, with the following title:

Implantable Drug Delivery Device For Providing A Desired Therapeutic Effect

Remarks

Amendments

Claims 1-18 were originally presented for examination. Claims 1-12, 14, 17, and 18 were withdrawn from consideration pursuant to a restriction and election of species requirement.

Claims 13-16 have been amended as shown above. No claims have been added.

The Examiner has indicated that the restriction/election requirement is made final. Applicants reiterate their traversal of the election requirement on the grounds previously stated. They also note that claim 14 has been amended to recite that the drug path preservation means has a storage means for the substance for resisting fibrous occlusions and that this substance comprises poly(glycine-valine-glycine-valine-proline). Accordingly, Applicants submit that claim 14 should be included in the claims under examination. The Examiner is requested to remove his withdrawal of claim 14 from examination.

The Examiner has included a lengthy statement regarding the proper content of an abstract of the disclosure in the Office Action. However, he has not indicated that any action needs to be taken in the present application. Accordingly, no amendments have been made to the Abstract.

The Examiner has indicated that the title of the application is not descriptive. Applicants have amended the title as shown above. Support for this title may be found at paragraph [0028] of the published version of the application (i.e., 2004/00343381 A1).

The Examiner has indicated that, with regard to claims 13 and 16, "...the Applicant has invoked 35 U.S.C. 112 6th paragraph by using 'means for' language reciting function and, not reciting sufficient structure of the means referred to in the specification." Applicants note that the Examiner has neither rejected nor objected to these claims on this basis. Accordingly, Applicants request clarification form the Examiner with regard to what, if any, objection/rejection is being applied to these claims.

Applicants also note that they have amended claim 13 to recite additional that the drug delivery preservation means comprising a substance for resisting the fibrous occlusion proximate the drug delivery ports. They have amended claim 14 to recite that this

substance comprises poly(glycine-valine-glycine-valine-proline). They have amended claim 15 to make its introductory portion consistent with claim 13. The have amended claim 16 to recite that there is an effective amount of the substance for resisting fibrous occlusions in the drug delivery ports. It is submitted that these amendments do not introduce any new matter, are fully supported by the specification and place the claims in condition for immediate allowance.

Rejections

The claims have been rejected under 35 U.S.C. 102(b) over U.S. patent 5,752,930 (hereinafter Rise) and U. S. Patent 5,041,107 (hereinafter Heil). Applicants traverse these rejections and submit that neither of these references discloses each and every element of the claims.

With regard to Rise, the Examiner argues that, among other things, this reference discloses a drug delivery path preservation means for delivering a substance that is capable of resisting fibrous occlusions through the drug delivery ports. Specifically, he cites column 3, lines 6-13 in support of this argument. Applicants disagree with the Examiner's analysis.

Rise discloses a device that can be used to infuse equal volumes of agents to spaced sites. A list of such agents is recited at column 3, lines 6-13. However, none of these agents is identified or described as a substance that is capable of resisting fibrous occlusions at the delivery site (i.e., the ports). In fact, Rise is entirely silent with respect to the problem addressed by the Applicant's invention. Rise fails to either recognize or mention that fibrous occlusion can be, or is, an issue that needs to be addressed. As a result, Rise fails to teach either the presence of a drug delivery path preservation means or the use of a substance that is capable of resisting fibrous occlusions at the drug delivery ports. Consequently, Rise fails to support the rejection of claims 13-16 under 35 U.S.C. 102(b).

With regard to Heil, the Examiner argues that, among other things, this reference discloses a drug delivery path preservation means for resisting fibrous occlusion of the drug delivery ports comprising means for delivering a substance that is capable of resisting fibrous occlusions through the drug delivery ports. Specifically, he cites column 1, line 65-column 2,

line 5 and column 4, lines 6-13 in support of this argument. Again, Applicants disagree with the Examiner's analysis.

Heil discloses an electrically controllable, non-occluding, body implantable drug delivery system. This system employs a self-sealing slit as a drug delivery site. Heil teaches that the slit is self-sealing (see, col. 2, lines 22-23; col. 3, lines 52-56; col. 4, lines 6-12; and col. 4, lines 38-43). This self –sealing property is achieved by either (a) providing a cut at an angle to the wall of the device so as to increase the amount of wall material intersected by the slit and prevent the ingress of blood or other tissue, or (b) providing a port covered by a membrane or film that acts as a physical barrier to the ingress of blood or other tissue. Thus, while Heil does disclose preventing occlusion of the drug delivery slits, he discloses that this is accomplished by a means a physical barrier and not by the delivery of a substance that resists fibrous occlusion. Consequently, Heil does not teach at least one required element of the claimed invention and therefore fails to support the rejection of claims 13-16 under 35 U.S.C. 102(b).

Conclusion

Based on the preceding comments, Applicants submit that they have shown that claims 13-16 are patentable over the Rise and Heil references. The request reconsideration of the rejections and allowance of all claims.

The Examiner is invited to contact the undersigned, at the Examiner's convenience, should the Examiner have any questions regarding this communication or the present patent application.

Respectfully Submitted,

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